



ALERT

News from the UFMCC
on AIDS Legislation, Education, Research and Treatment.

**Peptide T:
New Access Obstacles**

MARCH, 1991

Editor: Rev. Dr. Stephen Pieters

*(by John S. James; reprinted from AIDS
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For several months there have been increasing reports of difficulty in obtaining peptide T, an experimental treatment which is generally agreed to be safe and is in clinical trials. Recently the situation came to a head when two buyers' groups had their supplies cut off, due to Federal action against two different suppliers; in one of these cases, Ron Woodruff of the Dallas Buyers' Club sued the FDA, and lost in Federal Court in San Francisco. We started investigating, but soon learned that Treatment Issues, the treatment newsletter published by Gay Men's Health Crisis in New York, was already working on this problem. "Peptide T Access Blocked," by Wayne Kawadler, was published last week in Treatment Issues, volume 5, number 1, January 10, 1990.

[Note: To obtain a copy, send a note asking for the peptide T issue to: GMHC, attn: Medical Information, 129 West 20th St., New York, NY 10011, or call Wayne Kawadler at 212/337-1950. Also note: Treatment Issues is published ten times a year by Gay Men's Health Crisis. There is no charge for a subscription, but a \$20 per year contribution (\$40 international) is suggested if possible. A \$10 contribution is suggested for all back issues, for the last three years. To request a subscription, write or call to the number above. Note that number is only for Treatment Issues; for other AIDS information, call the GMHC hotline at 212/807-6655.]

We will not restate Mr. Kawadler's article, but it included the following points:

* FDA agents recently visited Peninsula Laboratories, in Belmont, CA, and told them that some of their peptide T, sold for animal research, "was actually being used by people and that the commerce must stop." [Note: Peptide T, like most experimental drugs, can be sold as a chemical for research or industrial purposes without advance approval; but if intended for human use, it can only be sold to someone with an IND (Investigational New Drug approval), i.e., permission from the FDA to conduct human trials.] This FDA action against Peninsula Laboratories led to the unsuccessful lawsuit by Ron Woodruff. Peninsula Laboratories had previously provided peptide T used in clinical trials.

* CarlbioTech, a pharmaceutical company in Denmark, recently received a contract to provide peptide T for a clinical trial at the University of Southern California. At about the same time, the FDA wrote to CarlbioTech and told them not to sell peptide T to anyone without an IND.

* The FDA has a well-known policy of allowing importation for personal use of limited amounts of drugs approved elsewhere but not in the U.S. under certain conditions. Apparently peptide T does not meet the guidelines for this policy, however, since it is not approved as a drug in any country.

* One clinical trial of peptide T now recruiting - a five year study at Yale for intravenous drug users - will enroll 24 volunteers per year. The protocol for the study at the University of Southern California is not yet final; current plans are for a six-month placebo study to enroll 150 volunteers. [We called the U.S. AIDS Clinical Trials Information Service, 800/TRIALS-A, and it had no information on peptide T trials now recruiting.]

COMMENT

Peptide T has been a hidden but appalling scandal for years. AIDS Treatment News first covered this drug four years ago, on January 16, 1987 (issue #22). At that time we reported that the drug had been given to four terminally ill patients in Sweden, and their condition had improved. We concluded that January 1987 article with an unfortunately prophetic paragraph:

"The public, through its AIDS, medical, and other public-service organizations, must continue to watch the development of peptide T, as well as other treatment research. In the past, too many promising AIDS treatment leads have been strangled in red tape or left on the shelf to collect dust instead of being tested promptly. Only continuing public vigilance can make sure it doesn't happen again."

Later, we heard a credible (but not confirmed) report that the Swedish research had been stopped by U.S. pressure.

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"PEPTIDE T" (cont'd)

It would take a book to trace the convoluted history of peptide T and investigate the many allegations of wrongdoing in its history. What happened to this drug is a grotesque microcosm of problems with drug development in this country. We do recommend such a study for a serious researcher; many hundreds, if not thousands, of pages of documentation are available. (For starters, see "Peptide T" in Treatment Issues, volume 3, number 1, February 6, 1989, published by Gay Men's Health Crisis, New York; also see "Peptide T and the AIDS Establishment" Boston magazine, June 1990).

Does the drug work? Our understanding is that it was originally intended to be an antiviral, and did show such activity in laboratory tests; the mechanism of action was believed to be similar to that of soluble CD4, i.e., preventing the virus from binding to and entering uninfected cells. But human tests which looked for antiviral activity were disappointing, and as a result, some researchers lost interest. Clinical trials have, however, repeatedly found neurological or other symptom improvements.

And personal reports we have received do suggest that the drug is helping - even if the mechanism is not known. For example, one of the people whose supply was recently cut off told us that he had been trying AIDS treatments for years, and had been through the "placebo effect" many times, enough to tell that his improvement with peptide T was not just a psychological effect from trying a new treatment.

We do not know how difficult it will be to get peptide T in the future. Unfortunately, the drug is rather expensive. It is usually administered by injection but it can also be prepared for nasal use, although that route is less efficient.

One big unanswered question is why would the FDA move against peptide T now? Everyone agrees the drug is safe. Furthermore, as far as we know, it is not being and has not been promoted. Instead, a few people learned that the drug was especially helpful for them - sometimes by volunteering for FDA-approved trials and then having their drug cut off when the trial ended - and quietly found ways to obtain a supply, either from U.S. or international sources. This system has continued for many months, if not for years, and as far as we know there have been no problems, no complaints. When there are many real problems to worry about, why would the FDA move now on a non-problem, when doing so will not do anyone any good, and may cause some people serious harm?

Until now the AIDS community has had only a sporadic interest in peptide T, because other issues are more important - for example, the early evaluation of ddC and

ddI - and beyond that, the development of workable efficacy standards for an epidemic emergency. The new generations of drugs now beginning human trials - from Merck, Boehringer Ingelheim, Hoffmann-La Roche, and a number of other major pharmaceutical companies - must have a rational development path, so that they do not waste the two years or more that the current system requires. Our main focus must naturally be on the most critical issues.

But access issues will not go away. For no matter what happens in FDA and drug-development reform, for years to come there will be many people who face death or irreparable injury because of lack of approval of treatment they need, when they are in fact right about their need for the drug, and the FDA and its experts are in fact wrong (or, more commonly, have not yet evaluated the drug, or even seen or tried to see the data). The FDA - suggested alternative of an individual compassionate IND is seldom available for AIDS. No community can abandon its people when they are sacrificed for bureaucratic convenience.

One of the problems we will face is bad court decisions left over from the decade-old battle against laetrile, a dubious cancer remedy. Under decisions of the U.S. Supreme Court (and also of the California Supreme Court), patients and their physicians have no right to treatment access; instead, the FDA makes that decision (but only when pharmaceutical companies, for their own reasons, ask it to). If the system is corrupt or ineffectual, or if the experts are incompetent, mistaken, or (most commonly) just too busy, then the patient has no recourse except to die or obtain treatment underground.

It is important to realize that this monstrous outcome occurred because the courts were asked to decide the wrong question. Laetrile advocates proposed that persons terminally ill should have the right to try anything, since the alternative was death. This position hardly seems unreasonable. But the problem is that the courts saw that they were being asked to put the terminally ill outside of the regulatory process entirely, in effect declaring open season for any hustler ready to take advantage of their desperation. This the courts were unwilling to do.

What the courts should have been asked instead was to give the ultimate access decision, in extreme cases, to the patient and physician - but to clearly distinguish this right of access from the marketing or promotion of unproven drugs. Currently, the laws control both drug access, and drug marketing (forbidding unsupported claims); but the mainstay of unapproved-drug regulation is in fact the control of claims (at least in California, which has some of the strictest health-fraud regulation in the nation). In one case, for example, a California physician was arrested after treating a patient with a

drug the physician had invented. We heard later that State authorities said they did not object if the patient continued to receive the treatment, by getting a pharmacist to formulate the drug; their objection was to statements made by the physician to patients, apparently heard by an undercover agent. We do not propose this case as a model; it does, however, illustrate the difference between control of access and control of claims. We suspect that if the courts had been asked to respect the autonomy of the terminally ill, but without at the same time removing them from regulatory protection, the decisions might have been different.

Unfortunately, it takes a long time for court rulings to change. One resource we should mention for those who have to fight the access issue now is the book Catastrophic Rights (subtitled Experimental Drugs and AIDS), by John Dixon, president of the British Columbia Civil Liberties Association (published by New Star Books, Vancouver, 1990). The phrase "catastrophic rights" refers to expanded rights of treatment access by persons who are catastrophically ill; the book develops this concept through discussion and analysis of relevant legal, medical, and scientific issues.

Above all, we believe that the best single strategy for the AIDS or other patient communities in fighting for treatment access is the development of medical consensus. When mainstream, respected experts who are familiar with a treatment have a well-supported belief that the treatment is valuable, then courts are reluctant to stand in their way. But we must also remember that while medical consensus will defeat most philosophical obstacles to treatment access, it will often not defeat the commercial and practical ones - as illustrated by drugs like fluconazole and EPO, which were not readily available until long after physicians realized they needed them. Nothing will replace continued hard work by activist and medical organizations to discover the real source of the obstacles, and ways to eliminate or circumvent them.

You Are Not Alone December, 1990

(by Larry Richards)

This is a personal letter to my friends who are involved with the HIV virus, or who are interested in my involvement in HIV vaccine research. I want you to know that you are not alone in fighting this disease, that there are several people working quite hard beside you.

I want to emphasize that there ****IS**** renewed hope in developing a vaccine for AIDS, both as a preventive for HIV negative people, by giving them immunity should they become exposed to the virus, and for HIV positive people, by providing additional immunity to that which they are already creating.

Because of the nature of the virus (it can hide inside cells and thus be protected from discovery), there may not be a way to completely rid the body of the virus, but there is hope to be able to control it and allow people to thus live with the virus, such as with diabetes.

It is interesting to note that at this time last year there were only three technologies being investigated to discover a vaccine. Now, there are five different ones and there are 12 companies trying to make a vaccine.

As most of you know, I am currently involved as a volunteer in a clinical research program to test an AIDS vaccine. This program is conducted by the National Institute of Allergies and Infectious Diseases (Clinic) on the campus of the National Institutes of Health (NIH) in Bethesda, MD outside of Washington, DC. I have been in the program 19 months now and have received 5 injections of the vaccine called GP160.

I am currently producing four different kinds of antibodies to the envelope proteins of the HIV virus: gp160, gp120, gp41 and p88. All but the last one are the same that HIV+ people create. We don't know where the last one comes from, but I'm making it!

The program has been underway for 3-years now and is the first vaccine program with human trials. To date there has been NO significant side effects or toxicity among the 140 male HIV- volunteers, most of whom are gay. (THIS IS GOOD NEWS). Because this program is still underway, little has been reported, hence the reason you may not have heard about the program.

ADDITIONAL GOOD NEWS: things were going so well in Spring 1990 that the program was expanded and I was asked to be a part of it. I was glad to continue. This meant additional injections, time, flying, commitment, etc. The expansion called for boosters every 6 months (May and November) and a flying schedule of 4 months on and 2 months off. During the off-time I would mail in my blood to the Clinic. I expect to be active in the program another year and a half or so.

If you haven't seen me in a while, it may be because I haven't been making my monthly visits to the Clinic from mid-August to mid-November. That has changed now as I have flown about 30,000 miles in the last 30 days, most of which were for the program.

When I was scheduled to receive my November booster, the Clinic wanted me to travel 4 times in 5 weeks to Washington during the holiday season; the first and fourth trips were the usual November and December visits, the other two were extra visits to donate blood for additional research to see which parts of the virus my antibodies are attracted to.

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"You Are Not Alone" (cont'd)

As well, my work took me to Washington and San Francisco during this time, and I had a vacation planned to Hawaii. I spent very little time there as I returned to San Diego the next day (less than 18 hours on the ground) due to a medical crisis with my grandmother.

During my November 14 trip to the Clinic, a time when I was only in Washington for 9 hours, I received a 5th injection of the vaccine. While there, I was asked to go to the NIH Dental Clinic to donate saliva for a test to see if my antibodies show up in saliva. I went back to the Dental Clinic during my December 10th visit for a follow-up session. My philosophy on tests is: if it doesn't hurt, I'll do whatever I can to help the cause.

I want to extend a word of special thanks to many of you who have helped me participate in the program. From San Diego there is Ray, Bud, Octavio, Louis, Eric and Eric. From Washington there is Rev. Larry, Darryl & Chase, Tom, Gerald, Bob, Jeff, Tim & Brian, Frank, Michael and the MCC Washington congregation and their HIV support group.

1991 International AIDS Candlelight Memorial

Mobilization Against AIDS is actively seeking cities and towns around the world that will participate in the eighth annual International AIDS Candlelight Memorial, which will occur on Sunday, May 19, 1991. Last May saw over 200 cities in 31 countries take part in AIDS Candlelight Memorials, which consist of locally organized public ceremonies honoring people lost to AIDS and demonstrating solidarity with all those infected with the HIV virus.

Mobilization Against AIDS, the California-based AIDS lobby group that serves as the coordinating agency for the International Memorials, is also announcing the launch of its "First Families Campaign." Mobilization is asking leaders around the world to follow the example of President Bush and First Lady Barbara Bush, who during last year's AIDS Memorial placed lit candles in the windows of the White House.

"In far too many places, AIDS is a taboo subject," said Paul Boneberg, Executive Director of Mobilization Against AIDS. "To have a people's leader publicly acknowledge the AIDS crisis through the symbolic act of placing a lit candle in the windows of his or her official residence will serve as a major victory in the fight to make AIDS a subject of public discussion and debate. Experience has shown that AIDS-related discrimination can only be fought when the topic is confronted head on. The First Families Campaign will do just that."

Mobilization is particularly interested in initiating Memorials in Eastern Europe and in Third World nations, and is soliciting contacts in those countries. For further information on organizing a 1991 Memorial in your community, or assisting Mobilization in enlisting your mayor, governor or head of state in the First Families Campaign, contact the International AIDS Candlelight Memorial at 1540 Market Street, Suite 160, San Francisco, CA 94102; CALL 415/863-3676; FAX 415/863-4740.

Studds Wins Seat On Key AIDS Committee

Washington, D.C. -- U.S. Rep. Gerry E. Studds (D-MA) was chosen unanimously by his colleagues to serve on the prestigious and powerful House Committee on Energy and Commerce.

Congressional Democrats awarded Studds one of only four Democratic vacancies on the Committee, which has jurisdiction over a broad range of domestic issues, including federal AIDS policy. Rep. Studds expressed gratitude for his selection, which came despite stiff competition from other Members, and pledged to use his new post to "help my own constituents and the rest of America address some of our most basic needs."

Studds listed his three top goals as "national health insurance; increased funding for AIDS education, research, and care; and a sensible national energy policy."

"I have fought long and hard for a rational federal response to the AIDS epidemic," Studds said. "And I have long been frustrated by the seeming inability of many federal officials to grasp the seriousness - and the scope - of HIV disease. Now, as a member of the Committee with direct jurisdiction over the issue, I will have more tools with which to fight. I also intend to raise a little hell about why Americans pay far more for far less medical care than those in other industrialized countries and I want to know why we don't have a national energy policy after all these years and why energy conservation and alternative energy sources have been shortchanged."

"This new assignment will give me an opportunity," Rep. Studds said, "to work in literally dozens of new areas - and to help focus much greater urgency and compassion on our national AIDS policy. It is a great step forward and I look ahead eagerly to the challenges of the next two years."

In addition, Rep. Studds will continue to serve as the second ranking Member of the House Committee on Merchant Marine and Fisheries, where he is expected to win re-election as Chairman of the Subcommittee on Fisheries and the Environment.